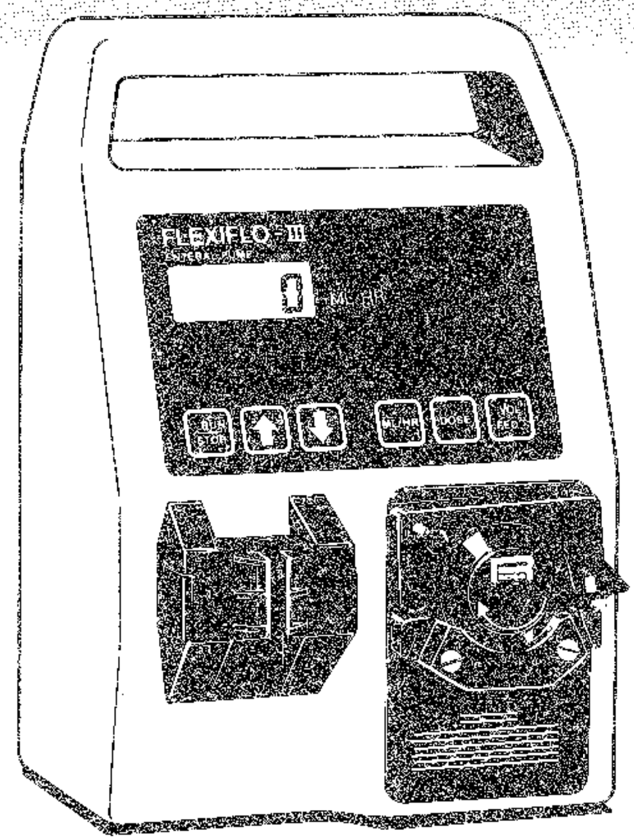
Flexiflo®-III Enteral Nutrition Pump

Operating Manual

For Enteral Use Only
Not For Parenteral Use



ROSS MEDICAL NUTRITIONAL SYSTEM®

ROSS PRODUCTS DIVISION
ABBOTT LABORATORIES
COLUMBUS, OHIO 43215-1724 USA

17586.7930 Rev 3/97 PAN 7128
LITHO IN USA

Uniquely designed and constructed, the FLEXIFLO®-III Enteral Nutrition Pump is a microprocessor (computer)-controlled, rotary, peristaltic pump that provides accurate delivery rates and has large, easy-to-read displays and simple controls. The FLEXIFLO-III Pump is used with other components of the FLEXIFLO Enteral Delivery System to provide safe, accurate control of enteral feeding at an affordable cost.

PRECAUTION: This pump is designed to deliver only a liquid enteral feeding product (standard liquid product, infant formula, or reconstituted powder product that has been thoroughly mixed into solution).

The FLEXIFLO-III Pump offers features such as:

1. No-flow alarm (tube occlusion/empty container)
   Some pump models will tie in with hospital nurse-call system
2. Accuracy to ± 10% with enteral products (see page 13 for details)
3. Fully charged battery operates for approximately 8 hours at 300 ML/HR
4. Low-battery alarm
5. Flow-rate selection from 1 to 300 ML/HR in 1 ML/HR increments
6. Volume-fed accumulation display
7. Dose setting
8. Self-checking capability
9. Automatic retention of values until pump power is turned off
10. Sequential controls that prevent inadvertent rate change

LIMITED WARRANTY PLAN

Ross Products Division, Abbott Laboratories warrants the FLEXIFLO®-III Enteral Nutrition Pump against defects in material and workmanship for a one (1) year period from date of delivery. This warranty is valid only to the original purchaser and does not extend to any product, or part thereof, which has been subjected to accident, alteration, damage, misuse, repair by other than Ross authorized representatives, or has not been operated and maintained in the manner prescribed in the Operating Manual or which at the time of pump failure was being used with pump sets or containers other than Ross pump sets and containers. Examples of damage or misuse include, but are not limited to, pumps that have been dropped, have had fluid spilled into or onto the casing, have been submerged or have had the back removed.

In no event shall Ross be liable for any incidental, indirect or consequential damages in conjunction with the purchase or use of the pump.

Ross reserves the right to repair or replace (at its option) any pump that fails to meet the foregoing warranty.

THE WARRANTIES HEREUNDER ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE.

INDICATIONS FOR USE

The FLEXIFLO®-III Pump can be used for adult and pediatric patients provided the patients can tolerate a feeding range within the pump operational specifications. Those specifications are:

- The flow rate range is 1-300 mL/hr in 1 mL/hr increments
- The flow rate accuracy is ±10% (see page 13 for details).
- The occlusion pressure limit is 23 psi nominal.

If these specifications are not appropriate for a given patient, the FLEXIFLO-III Pump should not be used.

PEDIATRIC USE

CAUTION

Do not use this pump for feeding infants under 12 months of age. In addition, use in all pediatric patients 12 months of age or older must be carefully evaluated. All enteral pumps have the potential to bolus-feed, which is an important consideration in feeding volume-sensitive patients. The rate of feeding should be 25 mL/hr or greater, and a volume of product no more than four times the hourly feeding rate should be hung.

The decision to use this pump in a pediatric patient should be made in conjunction with a pediatrician.

PRECAUTIONS

Confirm proper placement and function of the enteral feeding tube before initiating feeding

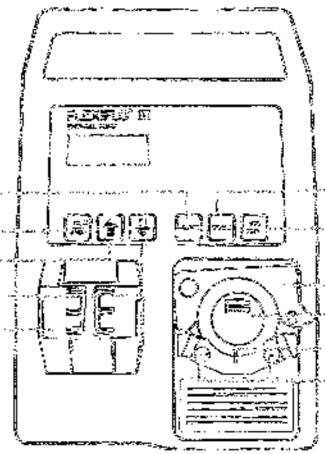
Before leaving a pump-fed patient unattended, verify the following:

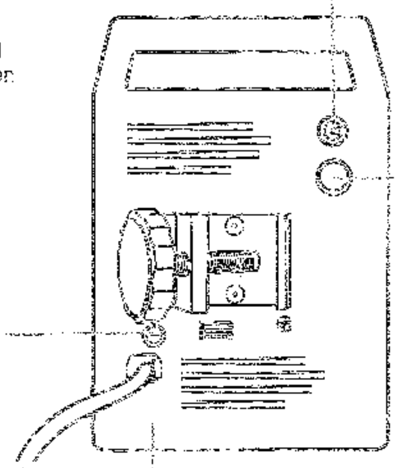
1. Rotor and rotor cover are clean. Failure to thoroughly clean product build-up around rotor may cause product overdelivery.
2. Confirm rotor cover moves freely up and down, and returns to a fully closed (down) position before starting pump.
3. Rotor is firmly seated on pump.
4. Confirm that tubing guide is mounted tightly against pump.
5. Pump-set tubing is properly placed on the rotor.
6. Feeding is being administered at the prescribed rate.

Failure to do so may result in an uncontrolled feeding rate, which may lead to vomiting and/or aspiration.

Pump set and container should be replaced as needed, or at least every 24 hours, to avoid product-contamination problems. For single use only

Here is a simple explanation of the switches, displays and alarms and their functions. Understanding them is necessary for successful operation of the pump.





Power

Voltage:	108 to 130 VAC, 45-65 HZ, 1 Phase
Power:	6 watts
Fuse:	¼ AMP, SAG type
Line Cord:	Hospital grade, nondetachable (10 feet)
Leakage:	Less than 100 microamps

Mechanical

Height:	9.7 inches
Width:	7.0 inches
Depth:	5.5 inches (9.5 inches with pole clamp)
Weight:	7.5 lbs

Operational Specifications—Flow Rates

Range:	1-300 mL/hr
Increments:	1 mL/hr
Accuracy:	±10% with measured flow rates of 1 liter of Ensure®, Osmolite® or Jevity®* (20 to 300 mL/hr) using FLEXIFLO® III Pump set at zero back pressure (atmospheric). *Individual accuracy ranges beyond this value may be encountered due to the viscosity of the enteral product and the pump set used. To check, see page 10.
Occlusion Pressure:	23 psi nominal

Battery Operation

Type:	Rechargeable sealed lead acid
Voltage:	6V
Expected Life:	When fully charged, approximately 8 hours at 300 mL/hr.

The battery manufacturer recommends that the battery be used at least once every six months for best performance and battery life. After extended storage periods and before initial use on battery power, the pump must be plugged into an AC power source for a minimum of 12 to 15 hours.

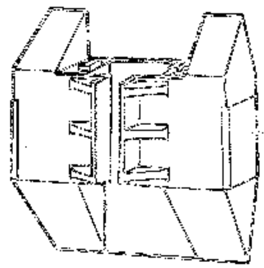
Standards

Designed and manufactured to meet requirements of UL 544 (1976).

CLEANING

DROP DETECTOR

- Clean with cotton swab and warm, soapy water. Dry thoroughly. Be sure no soap film or residue is left on lenses. DO NOT CLEAN WITH ALCOHOL.



Drop Detector

STORAGE

- The pump should be stored away from excessive heat, cold or humidity.
- Be sure ON/OFF switch is in the OFF position.

SERVICE

This FLEXIFLO®-III Pump is highly reliable. As with any electromechanical device, however, minor problems may occur. In the event of a pump malfunction, need for technical assistance or parts, please contact Ross Products Division, Abbott Laboratories.

BEFORE CALLING, DO A FEW SIMPLE CHECKS:

1. Check for proper electrical hookup. (Is pump plugged in? Is electrical outlet functioning? Is battery properly charged?)
2. Be certain that the DC power ON/OFF switch on rear panel of pump is ON
3. Be sure the FLEXIFLO-III Pump Set tubing is properly positioned over the rotor, with each of the plastic connectors in the tube-guide slots, and that the rotor cover is closed.
4. Be sure that the clamp on the pump set is open fully.
5. Be sure the drop detector is clean and the sight chamber is not overfilled or covered with a film of product.
6. Be sure the tubing, pump rotor, rotor cover and drop detector are clean and free of grease, oil and product.
7. Be sure the rotor and rotor cover are properly seated and that threaded screws on the tubing guide are securely tightened.

VISUAL DISPLAYS AND AUDIO ALARMS

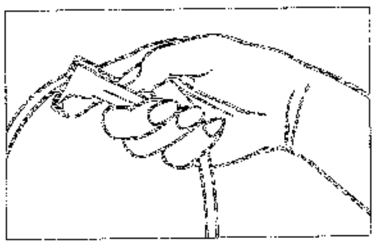
SWITCH:	FUNCTION:
RUN/STOP	Turns pump on or off but does not cause pump to lose DOSE or VOL FED data. Clears all visual and audio alarms.
UP-ARROW	Increases flow rate in mL/hr or DOSE in mL. Operates only in STOP mode.
DOWN-ARROW	Decreases flow rate in mL/hr or DOSE in mL. Also resets the VOL FED to zero. Operates only in STOP mode.
ML/HR (flow rate)	In STOP mode, press ML/HR, then UP-ARROW or DOWN-ARROW to select flow rate. In RUN mode, press ML/HR to display flow rate. **Pump will not operate without a setting for ML/HR.**
DOSE (volume in mL to be fed)	In STOP mode, press DOSE, then UP- or DOWN-ARROW to select volume to be fed. In RUN mode, press DOSE to recheck what was selected as volume to be fed. (Display holds for 3 seconds.) Pump will operate without a DOSE selected (DOSE set at zero).
VOL FED (volume in mL that has been fed at any time up to when DOSE is reached)	In RUN mode, press VOL FED to recheck the amount that has been fed up to that point. (Display holds for 3 seconds.) Press DOWN-ARROW to reset volume to zero so that additional product may be fed--up to volume that is set as DOSE.

LED DISPLAY AND AUDIO ALARM:	FUNCTION:
NO FLOW	Pump stops because flow has stopped for some reason. Check for empty container or flow restriction (closed clamp, clogged indwelling tube).
COVER OPEN	Pump stops if rotor cover is opened.
LOW BATT	Battery voltage is low. Pump will run approximately 30 minutes.
DOSE COMP	Planned total dose has been reached. Pump automatically stops. To feed additional product, press DOSE, then press UP-ARROW to display desired additional volume to be fed. Press RUN to restart the pump. To cancel DOSE selection feature and feed additional volume, press DOSE, then press DOWN-ARROW to display zero. Press RUN to restart the pump.

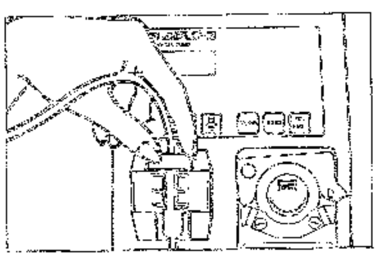
Before initial use on battery power and after extended storage periods, the pump must be plugged into an AC power source for a minimum of 12 to 15 hours. The battery manufacturer recommends that the battery be used at least once every six months for best performance and battery life.

Confirm that the tubing guide and rotor are mounted tightly against the pump and the rotor is firmly seated on the shaft. Check that rotor cover moves freely up and down, and returns to a fully closed (down) position before starting the pump.

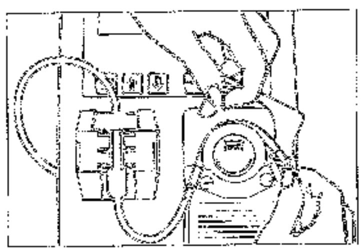
1. Attach pump to stand using pole clamp. Plug in cord if power is available. If using battery power, do not let battery run down. When the LOW BATT message appears, the battery has approximately 30 minutes of energy left.
2. Close CAIR® clamp (flow regulator)[†] on FLEXIFLO®-III Pump Set.



3. Attach the FLEXIFLO-III Pump Set securely onto filled enteral nutrition container, if it is not preattached. Suspend container to left or right of pump.
4. Place sight chamber into drop detector and seat in place.



5. **Remove** cover from adapter. Partially open clamp. Let fluid slowly enter sight chamber to create a reservoir. Do not fill above fill line. Overfilling will cause a false NO FLOW alarm. Allow product to expel air from tubing, then close clamp. (If sight chamber is overfilled, invert container while holding all tubing above sight chamber and container, open clamp, and allow solution to drain from tubing. Close clamp, suspend container and reprime.)
6. Open rotor cover and place first plastic connector into the left-hand slot below the pump rotor.
7. Loop the pump insert over the pump rotor.



8. Place second plastic connector into the right-hand slot below the pump rotor.
9. Close rotor cover and assure that it returns to a fully closed (down) position. Pump will not operate with rotor cover open. DO NOT OPEN COVER AFTER SETUP OR DURING OPERATION.

• CAIR® clamp manufactured under license from Adelberg Laboratories, Inc. Covered by one or more of the following US Patent Nos: 3,565,737; 3,993,468; 4,013,263; 4,047,694; 4,238,108; 4,181,476.

† If desired, clamp may be used to regulate flow rate by gravity, but all tubing must be completely disconnected from pump. This set delivers approximately 14 drops per mL.

For trouble-free operation, check the pump daily and clean immediately after spills occur.

While cleaning, pump should be turned off and unplugged.
Do not submerge, autoclave or ETO-sterilize the pump.

THE PUMP CAN BE CLEANED AS FOLLOWS:

HOUSING

- Clean outside surface with soft cloth and warm, soapy water.
- For general cleaning, use dishwashing detergent (non-chlorine-based) or isopropyl alcohol (not drop detector).
- For general disinfecting, use 70% concentration isopropyl alcohol.
- For disinfecting after exposure to AIDS or hepatitis, use 10% concentration of 5.25% sodium hypochlorite (household bleach). After exposure to tuberculosis, use 70% concentration isopropyl alcohol. These recommendations are not substitutes for official procedures that may differ among institutions.

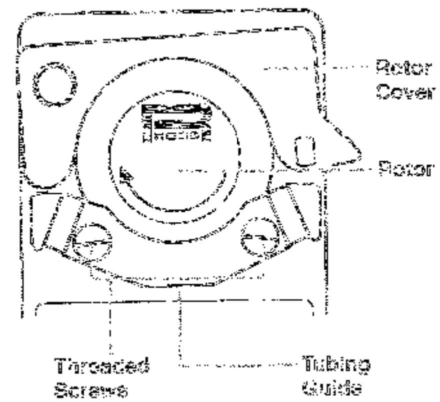
ROTOR ASSEMBLY

- Remove the tubing guide under the rotor by unscrewing the two threaded screws and pulling the guide straight out.
- Open the rotor cover. Then remove the rotor by pulling it straight out.
- Close rotor cover and remove by pulling it straight out.
- The removable pieces can be soaked in warm, soapy water. Check all four rollers on rotor to be sure each turns freely. Use a soft-bristle brush, dental floss or additional soaking to free up rollers. After cleaning, rinse and let parts air-dry.

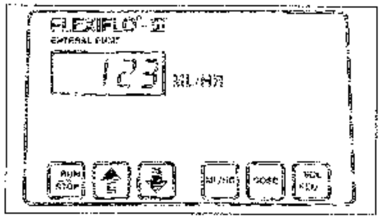
REASSEMBLE THE ROTOR AS FOLLOWS:

- Put rotor cover on first.
- Match flat part on shaft with flat part on rotor.
- Put rotor on, being sure to seat rotor against the pump by pressing firmly.
- Place tubing guide on threaded posts and tighten screws securely. **Failure to do so may result in uncontrolled feeding rate.**

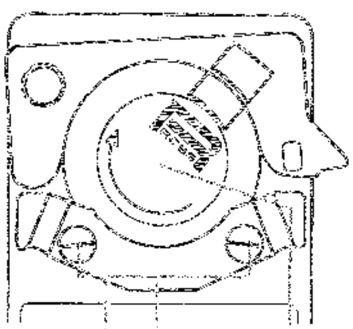
ROTOR COVER, ROTOR AND TUBING GUIDE ARE DESIGNED TO BE REMOVED FOR CLEANING.



PROBLEM	CORRECTIVE ACTION
Neither UP-ARROW nor DOWN-ARROW responds when switch keys are pressed to increase or decrease ML/HR, DOSE or VOL FED.	The UP-ARROW and DOWN-ARROW operate only when the pump is in STOP mode.



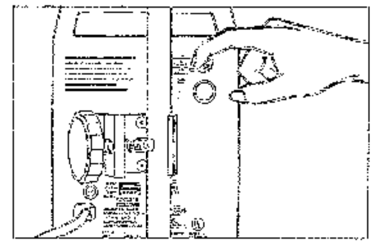
Flow rate is inaccurate.



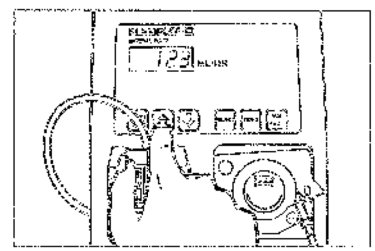
Flow Rate Setting (ML/HR)	Approximate Revolutions per Minute
36	1
108	3
180	5
252	7

1. To test flow rate, use the following procedure: Be sure to use a graduated cylinder for volume measurement--not an enteral container. Using Ensure® Complete, Balanced Nutrition™, Osmolite® Isotonic Liquid Nutrition or Jevity® Isotonic Liquid Nutrition With Fiber fill the container and set up pump per instructions Use a FLEXIFLO®-III Pump Set only
2. Confirm that the tubing guide and rotor are mounted tightly against the pump and the rotor is firmly seated on the shaft.
3. Be sure rotor and cover arm are free from product spillage and all four rollers turn freely.
4. Check that rotor cover moves freely up and down, and returns to a fully closed (down) position before starting the pump.
5. Check rotor speed with a watch. Place two pieces of tape–one on rotor, one on rotor cover–to help count revolutions, per illustration. Check rotor speed against the chart. If necessary, refer to **ROTOR ASSEMBLY**, page 11.
6. Start the pump and run for 15 minutes. Then run product into graduated cylinder for 1 hour and compare to rate set on pump. If flow rate is incorrect, try a new pump set and repeat procedure. Refer to **SPECIFICATIONS**, page 13, for accuracy rate.

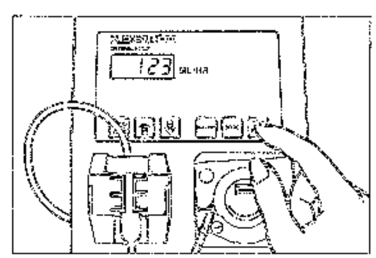
10. CONFIRM PROPER PLACEMENT AND FUNCTION OF ENTERAL FEEDING TUBE. Connect adapter to patient's enteral feeding tube (nasogastric, gastrostomy, etc).
11. Open clamp fully.
12. Switch power ON (back of pump). Pump will initiate self-test procedure.



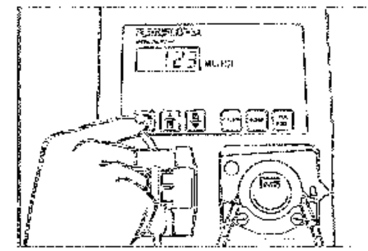
13. Select flow rate (ML/HR), using UP- or DOWN-ARROW.



14. If desired, set dose by pressing DOSE switch and then UP- or DOWN-ARROW. Set dose to zero, using DOWN-ARROW to override the DOSE function.
15. Press VOL FED switch and verify that volume is at zero; if not, press DOWN-ARROW to reset volume to zero.



16. Press RUN/STOP switch to start feeding.



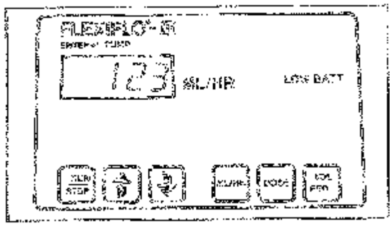
17. When feeding is complete, switch pump off.

NOTE: Pump stops and sounds an alarm automatically when the container is empty. If the DOSE function is in use, the pump will stop, sound the alarm and display the DOSE COMP message when the selected dose is reached.

PROBLEM / CORRECTIVE ACTION

PROBLEM

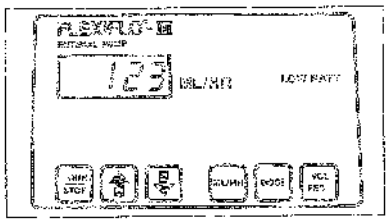
LOW BATT display appears when pump IS NOT plugged into a functioning electrical outlet.



CORRECTIVE ACTION

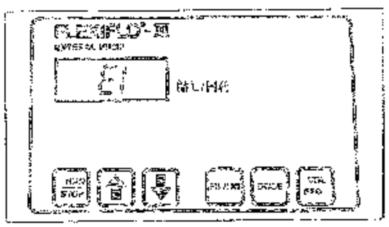
Recharge battery for 12 to 15 hours at a functioning AC outlet. Be sure electrical outlet is functioning by testing with another electrical appliance. If LOW BATT display still appears after 12- to 15-hour recharge, battery servicing is required. (Battery manufacturer recommends that the battery be used at least once every six months for best performance and battery life.)

LOW BATT display appears when pump IS plugged into a functioning electrical outlet.



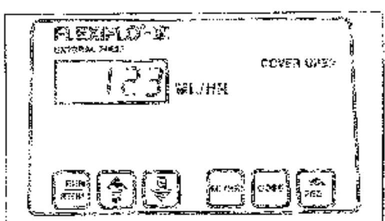
1. Check for blown fuse.
2. Check for defective power cord

E1, E2, E3 displays appear and pump does not run.



These displays indicate the pump has a self-diagnosed problem and needs technical servicing.

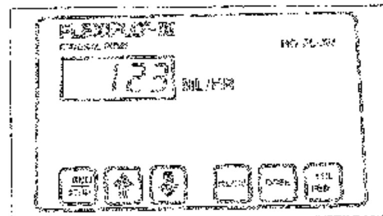
COVER OPEN display is visible.



Be sure no object is keeping the rotor cover open.

PROBLEM

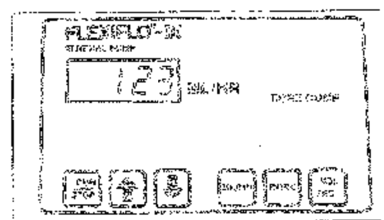
NO FLOW display is visible.



CORRECTIVE ACTION

1. If product is not flowing:
   a) Be sure clamp on pump set is open.
   b) Check for kinked, pinched or occluded pump-set tubing.
   c) When using a rigid feeding container, replace pump set if air filter is clogged.
   d) Check that indwelling feeding tube is not clogged.
2. Be sure that sight chamber on pump set is not more than ½ full.
3. Be sure container is not empty.
4. Be sure sight chamber is properly seated into drop detector.
5. Be sure drops are falling down the center of the sight chamber and not running down the sight-chamber wall.
6. Be sure sight-chamber wall is free from drops of product or condensation.
7. Be sure drop-detector windows are not dirty.
8. Be sure pump set is properly loaded (refer to INSTRUCTIONS FOR USE).

DOSE COMP display is visible.



Feeding amount entered in DOSE has been reached. Do one of the following:

a) Press RUN/STOP, then increase dose by pressing DOSE and then press UP-ARROW until desired new dose amount is displayed. Now press RUN/STOP switch to restart pump.

b) Press RUN/STOP, then repeat at same dose quantity by pressing VOL FED, then press DOWN-ARROW until zero is displayed. Now press RUN/STOP switch to restart pump.

c) Press RUN/STOP, then clear dose by pressing DOSE, then press DOWN-ARROW until zero is displayed. Now press RUN/STOP switch to restart pump.